

Group II: Claims 5-7 drawn to a method for preparing nanoscale or amorphous particles comprising (1) adding one or more active ingredients, solid fat and optionally one or more surfactants into a reactor, further adding the gas of a supercritical fluid so as to provide a sub critical or supercritical condition, and then melt-mixing the mixture by heating

Claims 1-2, 8-12 and 14-20 are considered to be “linking” claims and therefore belong to both Groups I and II.

The Applicant hereby elects to prosecute the invention of **Group I, claims 3-4 and 13** (including linking claims 1, 2, 8-12 and 14-20). However, the Applicant **traverses** the rejection on the ground that the two groups of inventions have unity of invention (37 CFR 1.475(a)).

The Examiner specifically states that “The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features...”. The Examiner asserts that “The common technical feature of the above groups is a method for preparing nanoscale or amorphous particles comprising the steps of (1) preparing a mixture comprising one or more active ingredients and solid fat and (2) and pressurizing the mixture comprising one or more active ingredients and solid fat to the critical pressure or more by adding the gas of a supercritical fluid into the mixture, and then removing the solid fat from the mixture by releasing out the solid fat together with the gas of a supercritical fluid” and that this is NOT a special technical feature under PCT Rule 13.2 because it is not novel. The Examiner supports this assumption with the teachings of US Patent 6471,993 and US Patent Publication No. 20060035350.

Under PCT Rule 13.2, the expression “special technical features: shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The special technical feature of the present invention lies in the preparation of nanoscale particles of active ingredients. Neither US Patent No. 6,471,993 nor US Patent Publication No. 20060035350 teaches such a preparation of nanoscale particles of active ingredients and thus the special technical feature is novel.

US Patent No. 6,471,993 ('993) discloses preparation of a polymer matrix and the incorporation of active ingredients into the matrix during its preparation process. '993 does not however teach the preparation of nanoscale particles of active ingredients by the method of the present invention. The porogens (such as triglycerides according to the Office action) disclosed in '993 are materials added to form voids in the polymer matrix and have no relation to the preparation and size of the particles of the active ingredients. In the method of the present invention, the solid fat is used as a solvent of the polymer and active ingredients (abstract) which is not disclosed in '993. The solidification of the mixture of the active ingredients and solid fat and the removal of the solid fat from the mixture contribute directly to the preparation and size of the nanoscale particles.

In addition, in regards to adding active ingredients, '993 suggests the following three methods (see section: "Methods of Incorporating Additives" (column 23)):

1. A solution or dispersion of additive particles is added to a mixture of polymer and porogens and mixed, and then only the porogens are dissolved out by using a solvent which dissolves the porogen but not the polymer, by which only the additive remains in the polymer matrix.

By this method, the additive exists in the polymer matrix as a mixed form with the polymer or in the voids. If it is added as a form of particle, it would be separated from the polymer and accordingly exist in the voids. In this case, the size of the additive particles will be determined not by the preparation process but by the original size thereof. In addition, if a solvent is removed from the mixture of polymer and additive very slowly as disclosed in '993, the resulting particles will not be of nanoscale size. That is, the porogens used in '993 do not contribute to the formation of nanoscale additive particles.

2. Additives are added to a solution of porogens, and the solvent is removed therefrom. The mixture is then subjected to a cryo-milling and mixed with a polymer solution to form a paste. Finally, porogens are removed by a porogen-soluble solvent to maintain additives in voids in the polymer matrix.

In this method of dissolving porogens in a solvent, adding the additive thereto and removing the solvent, if the solvent does not dissolve the additive, the particle size of the

additive would not change. That is, the particle size of the additive would remain the same before and after the process. On the contrary, if the solvent dissolves the additive and porogens, the particle size of the additive would be dependent on the condition and procedure of the process. However, the porogens in the method taught by '993 are not a solvent for the active ingredients and polymer. In the method disclosed by '993 the solvent is evaporated, and thus does not teach a method to prepare nanoscale particles.

3. Bioactive materials are entrapped in the voids of the polymer matrix by forming voids in the polymer matrix and adding the polymer matrix into a solution of bioactive material to adsorb the bioactive material.

This method has no relation to the preparation of particles of bioactive material.

In addition, the teachings of US Patent Publication No. 20060035350 do not make up for the deficiencies of the teachings of '993. The Applicant contends that Groups I and II share the same novel special technical feature which is distinguishable from the prior art and respectfully requests that the Restriction Requirement between Groups I and II be withdrawn.

In addition, Applicant's representative, Angela M. Domitrovich spoke with Examiner Dickinson via telephone on April 21, 2010 to confirm that this Restriction Requirement is for election of an invention and not a species election. Therefore, the Applicant reserves the right to pursue a divisional application for any non-elected invention.

Closing Remarks

If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-1970, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

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